Exhibit 23

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

****

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
**********	Civil No. 19-2875 (RBK/JS)
THIS DOCUMENT APPLIES TO ALL CASES	HON ROBERT B. KUGLER

****

- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

Continued Remote Videotaped via Zoom Deposition of JUCAI GE, held at the location of the deponent, commencing at 6:40 a.m. China Standard Time, on the 27th of May, 2022, before Maureen O'Connor Pollard, Registered Diplomate Reporter, Realtime Systems Administrator, Certified Shorthand Reporter.

– – –

GOLKOW LITIGATION SERVICES
877.370.DEPS
deps@golkow.com

REMOTE APPEARANCES:

MAZIE SLATER KATZ & FREEMAN, LLC
BY: ADAM M. SLATER, ESQ.
BY: CHRISTOPHER J. GEDDIS, ESQ.
103 Eisenhower Parkway
Roseland, New Jersey 07068
973-228-9898
aslater@mazieslater.com
cgeddis@mazieslater.com
Representing the Plaintiffs

MEYER WILSON CO., LPA
BY: LAYNE HILTON, ESQ.
900 Camp Street, Suite 337
New Orleans, Louisiana 70130
614-255-2697
lhilton@meyerwilson.com
Representing the Plaintiffs

HOLLIS LAW FIRM
BY: IRIS SIMPSON, ESQ.
8101 College Blvd., Suite 260
Overland Park, Kansas 66210
800-701-3672
iris@hollislawfirm.com
Representing the Plaintiffs

FARR LAW FIRM
BY: GEORGE T. WILLIAMSON, ESQ.
99 Nesbit Street
Punta Gorda, Florida 33950
941-639-1158
gwilliamson@farr.com
Representing the Plaintiffs

REMOTE APPEARANCES (Continued):

SKADDEN ARPS SLATE MEAGHER & FLOM LLP
BY: RICHARD T. BERNARDO, ESQ.
BY: ALLISON M. BROWN, ESQ.
One Manhattan West
New York, New York 10001-8602
212-735-3453
richard.bernardo@skadden.com
allison.brown@skadden.com
Representing the Defendants Zhejiang Huahai Pharmaceutical Co., Ltd., Prinston Pharmaceutical Inc., Huahai U.S., Inc., and Solco Healthcare US, LLC

SKADDEN ARPS SLATE MEAGHER & FLOM LLP
BY: CATHERINE I. MULLALEY, ESQ.
500 Boylston Street
Boston, Massachusetts 02116
617-573-4851
kate.mullaley@skadden.com
Representing the Defendants Zhejiang Huahai Pharmaceutical Co., Ltd., Prinston Pharmaceutical Inc., Huahai U.S., Inc., and Solco Healthcare US, LLC

PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP
BY: FRANK H. STOY, ESQ.
One Oxford Centre
Pittsburgh, Pennsylvania 15219
412-263-1840
fhs@pietragallo.com
Representing the Defendant, Mylan Pharmaceuticals, Inc.

REMOTE APPEARANCES (Continued):

BARNES & THORNBURG, LLP
BY: KARA KAPKE, ESQ.
11 S. Meridian Street
Indianapolis, Indiana 46204
317-231-6491
kara.kapke@btlaw.com
Representing the Defendants CVS Pharmacy, Inc., and Rite Aid Corporation

GREENBERG TRAURIG, LLP
BY: VICTORIA J. LANGTON, ESQ.
Terminus 200
3333 Piedmont Road NE
Suite 2500
Atlanta, Georgia 30305
678-553-2100
langtont@gtlaw.com
Representing the Defendants Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals SA, Inc., Actavis LLC, and Actavis Pharma, Inc.

Interpreter: Dr. Yang Shao
Check Interpreter: Phil Hughes

Also Present:

Stephanie Martin, Legal Assistant, Skadden
Bailey Pasho-Towns, Summer Associate, Farr

Videographer: Judy Diaz

INDEX

E X H I B I T S

- - -

DEPOSITION SUPPORT INDEX

- - -

Direction to Witness Not to Answer
PAGE LINE
None.

Request for Production of Documents
PAGE LINE
None.

Stipulations
PAGE LINE
None.

Questions Marked Highly Confidential
PAGE LINE
None.

P R O C E E D I N G S

THE VIDEOGRAPHER: We are now on the record.

My name is Judy Diaz. I'm a legal videographer for Golkow Litigation Services.

Today's date is May 27, 2022, and the time is 6:40 a.m.

This is the continuation of the deponent Jucai Ge.

All counsel will be noted on the stenographic record.

The witness and the interpreter are already under oath.

Counsel, you may proceed.

***

JUCAI GE,

having been duly previously remotely identified and sworn, was examined and testified as follows through the interpreter:

FURTHER EXAMINATION

BY MR. SLATER:

Q. Thank you. Good evening --

Page 137

good morning.
A. Good morning.
Q. I forgot to ask you last night, so I need to ask you a question. Rephrase.
As part of your preparation, did you have an opportunity to see the questions that you were to be asked during this deposition pursuant to the order entered by the judge?
A. I didn't have any chance to review the list of questions. However, I am aware of the topics on which I am supposed to testify. Those three topics I am familiar with.
Q. I'd like to ask you a few more questions about that e-mail, Exhibit 295 in Mandarin, 296 in English, and then we'll move on to something else. But I need to follow up on a few things you said at the end of the session last night.
A. All right.
Q. With regard to the 2013 patent that is referenced, do you know when that was first seen by anybody at ZHP?

Page 138

A. I did ask Jinsheng Lin and Peng Dong about that. According to Jinsheng Lin, he came across this patent when he was doing an online search regarding irbesartan, so he attached this patent to this e-mail. Therefore, Peng Dong become aware of that patent because of this e-mail.
Q. When did Jinsheng Lin do that search and find the patent?
MR. BERNARDO: Adam, you got cut off at the beginning, I'm sorry.
BY MR. SLATER:
Q. When did Jinsheng Lin do that search and find the patent?
MR. BERNARDO: Thank you.
THE WITNESS: According to Jinsheng Lin, he came across this patent around the time he was writing this e-mail.
Whether he conducted the online search while he was drafting this e-mail or several hours or several days before he was drafting this e-mail, I don't know. All I know is

Page 139

that at that time he was conducting an online search regarding the impurity found in the technical improvement for irbesartan.
He was trying at that time to make a comparison in toxicology where he came across this patent, so he attached this patent to that e-mail. He didn't tell me the exact time when he did the online search.
BY MR. SLATER:
Q. It's your best understanding that Jinsheng Lin found the patent in July 2017? Yes or no.
A. Yes.
Q. Had anybody else at ZHP ever found and read that 2013 patent before Jinsheng Lin found it in July 2017?
MR. BERNARDO: Object to the form of the question.
MR. SLATER: I'm going to reask. I'm sorry, Dr. Shao, I'm going to reask the question because counsel objected.

Page 140

BY MR. SLATER:
Q. Had anybody else ever read the 2013 patent referenced in Dr. Lin's e-mail before Dr. Lin found it in 2017 during his online search? Yes or no.
MR. BERNARDO: Object to the form of the question.
THE WITNESS: I didn't ask around in ZHP about the patent by approaching everyone in the company. I didn't ask people about that.
As for the e-mail itself, during the preparation, I did have a discussion with people like Min Li, Lihong Lin, spelled as L-I-H-O-N-G, last name L-I-N, Peng Dong, and Jinsheng Lin.
I did ask Peng Dong and Jinsheng Lin when they came across this patent.
According to Peng Dong, he became aware of this patent through the e-mail of Jinsheng Lin in the attachment. That's how he received

Page 141

the information.
As for Jinsheng Lin, when he was writing this e-mail, he was trying to make a comparison in toxicology, he did some online search, and he came across this patent.
Again, I did not ask everyone in ZHP about when they came across this patent.
Based on what I was told by Peng Dong, since he was in charge of the technology of valsartan and he was also the person in charge of the technical department at Chuannan site, to his knowledge, no one else knew about this patent in Chuannan.
BY MR. SLATER:
Q. Based on your investigation, nobody else in ZHP was aware of this patent before it was found by Jinsheng Lin? Yes or no, is that correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: As to my prior

Page 142

testimony, to the best of my knowledge, before Jinsheng Lin came across this patent, no one else in ZHP was aware of this patent.
However, I did not ask everyone in ZHP regarding this patent, which I already told you. Therefore, I don't know whether I can respond to this question with a simple yes or no.
BY MR. SLATER:
Q. The e-mail indicates that there is an extremely high GMP risk, which is also referred to as a quality problem, due to the formation of nitrosamine due to sodium nitrite quenching of sartans.
That is discussed in the e-mail, correct?
A. That is not correct.
Q. Looking at the second page of the e-mail, second-to-last paragraph says in part, "If it is confirmed as the above speculated structure" -- which is an N-nitroso compound -- "then its toxicity will be very strong, and there will be an

Page 143

extremely high GMP risk."
That's what the document says? That's what the words on the page say, correct? Please answer with a yes or no.
MR. BERNARDO: Object to the form of the question.
THE WITNESS: The document does say so, so that's correct. However, what the document says is inconsistent with your prior statement.
BY MR. SLATER:
Q. In that same paragraph, the second-to- -- rephrase.
In the second-to-last paragraph on the second page of the e-mail, Dr. Lin also recommends "the optimization of the valsartan sodium azide quenching process," correct? That's what the words on the page say, right?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: The document does include such a sentence. The document does include such a sentence.

Page 144

BY MR. SLATER:
Q. In the last paragraph on the second page of the e-mail, Dr. Lin points out that in the 2013 patent by the other company, "they proposed that the use of sodium nitrite quenching will result in the formation of N-nitroso impurities." Correct? That's what the document says, right?
A. That's not the original wording. I see that in that paragraph, there is a similar sentence just like that.
Q. In the last paragraph on the second page, Dr. Lin states that "other companies have paid attention to the quality problem very early on." That quality problem being the quenching with sodium nitrite resulting in the formation of N-nitroso impurities, correct?
MR. BERNARDO: Object to the form of the question.
BY MR. SLATER:
Q. That's what the document says, correct?
MR. BERNARDO: Object to the

Page 145

form of the question.
THE WITNESS: The document does say that other companies have paid attention to the quality problems very early on. However, that quality problem is the problem referred to in the patent, not your interpretation in the statement.
BY MR. SLATER:
Q. The quality problem referred to in the patent is that the use of sodium nitrite quenching will result in the formation of N-nitroso impurities, correct?
A. The patent mentioned that Impurity K will be formed.
Q. And the formation of Impurity K is the quality problem referred to, correct?
A. That is correct.
Q. Dr. Lin says at the end of the e-mail -- rephrase.
At the end of the e-mail, Dr. Lin says words to the effect of, "Leaders please pay attention to this issue."
He's telling those on the

Page 146

e-mail, including yourself, that this is an issue that needs to be addressed, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: I don't know what issue are you referring to. Could you be more specific in your question?
BY MR. SLATER:
Q. The last sentence of the e-mail says words to the effect of, "Leaders pay attention to this issue," the issue being the quality problem with sodium nitrite quenching resulting in the formation of N-nitroso impurities, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: That is incorrect. I believe it is very clear, after communication with Dr. Lin and reading his e-mail, that he heard from a friend of his that someone has already tested out Impurity K in our crude product. Therefore, he was asking the leaders

Page 147

to pay attention and find out whether there's also Impurity K in valsartan.
You cannot take the last sentence out of context. You have to interpret this sentence with the preceding sentences.
BY MR. SLATER:
Q. Dr. Lin referred at the top of the page to the fact that the impurity that was being seen in the irbesartan was similar to the NDMA that occurs in valsartan when quenched with sodium nitrite.
We've talked about that before. He said that up above, right?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: I believe I have already responded to your questions regarding this topic yesterday.
BY MR. SLATER:
Q. So the answer is yes, correct?
A. No, it's not like that.
Q. After this e-mail was sent, you testified last night that Peng Dong and

Page 148

Jinsheng Lin tested valsartan for Impurity K, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: I did not say both of them tried to test out Impurity K from valsartan yesterday.
What I said, also supported by the content of this e-mail, is that a friend of Dr. Lin's gave him the information that someone has already tested Impurity K from irbesartan, so he did some verification by consulting an analysis and failed to find Impurity K from irbesartan.
After he informed Peng Dong, Peng Dong was also aware of the result, that there was no Impurity K identified in an analytical result.
BY MR. SLATER:
Q. So it's your testimony that when Dr. Lin tested valsartan for Impurity K -- rephrase.
So -- rephrase.

Page 149

It's your testimony that when Jinsheng Lin tested the valsartan for Impurity K, the test showed that there was no Impurity K? Is that your testimony? Yes or no.

MR. BERNARDO: Object to the form of the question.

THE WITNESS: No, that's not what I said. What I said was Jinsheng Lin conducted analysis of Impurity K in our valsartan.

BY MR. SLATER:

Q. Was there Impurity K in ZHP's valsartan?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: During the recent communication with Jinsheng Lin, he told me that he failed to find any Impurity K in those batches he analyzed in our valsartan.

BY MR. SLATER:

Q. Do you know whether ZHP ever tested its valsartan manufactured with the

Page 150

zinc chloride process and identified Impurity K as an impurity? Yes or no.

A. What time frame are you referring to?

Q. Ever. Any time.

A. To the best of my knowledge, after 2018, Impurity K was identified after further analysis of our valsartan.

Q. After this July 27, 20- -- rephrase.

After this July 27, 2017 e-mail was sent by Dr. Lin, did ZHP test its valsartan manufactured with the zinc chloride process for NDMA before June of 2018? Yes or no.

A. No. At that time, we were not aware of the existence of NDMA.

Q. Is there any documentation of Jinsheng Lin or Peng Dong analyzing ZHP's valsartan for Impurity K before June of 2018?

A. They did conduct the analysis for confirmation. However, during the preparation, I did not ask them about the documentation of such confirmation. So I'll

Page 151

have to go back and check.

Q. We reviewed the entire document production in this litigation today and could find nothing indicating Peng Dong, Jinsheng Lin, or anybody else in ZHP evaluated valsartan for Impurity K before June 2018.

Are you aware of any such documentation in existence?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: To the best of my knowledge, since I work in the QA department, all I know is that for impurity verification or confirmation, the verification has to be done through methods such as LC-MS. For specifics, I believe we have to consult with the analytical personnel.

However, also to the best of my knowledge, for some impurity verifications, there would not be documentation such as chromatograms. Therefore, I believe we have to consult with the specific analytical

Page 152

staff.

BY MR. SLATER:

Q. Is it your understanding Jinsheng Lin used LC-MS testing to try to identify Impurity K in the valsartan in 2017?

A. According to Jinsheng Lin, after he sent out this e-mail, he conducted the analysis using LC-MS, and the analytical result showed that there was no Impurity K found.

Q. If anybody were to say that a pharmaceutical company could not have known that quenching the valsartan with sodium nitrite could result in the formation of N-nitroso impurities, for example, NDMA, that would be incorrect, since we know from the patent that another company in China knew that as of the time they drafted their patent in 2013, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: That's incorrect.

BY MR. SLATER:

Q. It's right there in the patent.

Page 153

It says it in the patent dated 2013 by this other company.

They figured it out, right?

MR. BERNARDO: Object to the form of the question.

MR. SLATER: I'll ask the question differently.

BY MR. SLATER:

Q. That's what the patent says. That's what the words on the page of the patent say, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: That's incorrect. The patent says that the Impurity K will be formed. The patent didn't say anything about the formation of NDMA. In fact, the patent didn't mention NDMA at all.

BY MR. SLATER:

Q. The patent says N-nitroso -- rephrase.

The patent refers to the formation of N-nitroso impurities. That's

Page 154

what the word on the page says, correct?

MR. BERNARDO: Objection to form.

THE WITNESS: In the patent it says the Impurity K is one of the nitroso compounds.

And regretfully, had the patent been written about the formation of NDMA, it would have mentioned NDMA.

But NDMA was not mentioned in the patent, and instead it said that Impurity K is one of the nitroso compounds.

BY MR. SLATER:

Q. The point is, doesn't this patent in 2013 -- this other company disclosed that the sodium nitrite quenching could create an N-nitroso compound impurity, correct?

A. No, that's not correct. The patent says it was for Impurity K, not nitroso compound impurities. While Impurity K is one of the nitroso compound impurity, the nitroso compound would include

Page 155

hundreds of different compounds.

Q. Before 2017, did ZHP ever test any of its valsartan for Impurity K? Yes or no.

A. To the best of the information that I collected, given that I didn't approach everyone in the company, the answer is no.

Q. The testing that Jinsheng Lin did in 2017 for Impurity K was required to be documented by cGMP because it was testing for a highly toxic impurity in the valsartan, correct?

A. That's incorrect.

Q. So it's your testimony as the director of quality assurance at ZHP that your company can test for highly toxic impurities that are suspected in your drug products and fail to document that testing or the results of the testing? That's your testimony now, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: That's incorrect,

Page 156

because according to Jinsheng Lin, he did conduct the analysis using LC-MS.

However, as for the documentation, I already told you I have to consult with specific analytical staff.

But he told me he used LC-MS for the analysis to analyze commercial batches.

As for the documentation, we have to confirm with specific analytical staff.

BY MR. SLATER:

Q. Pursuant to ZHP's SMPs, it was required that such testing be documented, correct?

A. As in my prior testimony, I already stated that this is an analysis and verification instead of a test.

Q. It was an analysis and a verification with an LC-MS testing method, correct?

A. That's correct. That's what he told me.

Page 157

Q. Am I correct that if a test was performed -- well, rephrase.
You would agree with me that such testing is required to be documented, correct?
MR. BERNARDO: Object to form.
THE WITNESS: As I told you before, I am not one of the analytical staff, and I didn't realize that you would ask for such specifics. So when I asked around to gather information, I did not ask for such details.
Again, what he did was analysis and verification, not a test. He simply conducted the analysis and verification based on the existing LC-MS method. I believe he must have the original chromatogram.
BY MR. SLATER:
Q. Why wasn't that original chromatogram produced to us in discovery?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: I'm not familiar

Page 158

with the discovery process and the production process, so I'm not sure whether the chromatograms were produced or not.
However, according to him, he did the analysis and verification based on the previous LC-MS chromatograms. For that I have to go ask specific analytical staff. I didn't realize that such details would be asked about this time.
MR. SLATER: Chris, let's go to the patent filed July 17, 2018, the Abstract, please.
Can you make that a little bigger, please, Chris?
Don't be so grudging. Can you get it a little bigger, or no?
MR. GEDDIS: Which part do you want?
MR. SLATER: Let's do the top half first with the date on it, etcetera.
Q. Okay. So I'm showing you a

Page 159

patent that was filed July 17, 2018.
MR. SLATER: And let's minimize it a little more so we can look at the title now.
You're going to just have to make it smaller. I can't read it.
You can just make it smaller, Chris, just so we can all see it.
That's fine, I'll take a shot. Perfect. Okay.
BY MR. SLATER:
Q. On the screen is a July 17, 2018 filed patent titled "Method for Synthesizing Valsartan," and you can see on the left side the inventors are listed. It includes Peng Dong, Jinsheng Lin, Min Li, and several other people.
Do you see that?
A. It's kind of blurry to me. Can you blow it up?
Now I see.
MR. SLATER: Let's go into the text, the first paragraph, please.
Perfect.

Page 160

Q. In the abstract --
A. Sorry.
Q. In the Abstract for the patent, a little more than halfway down, there's a sentence says, "The synthesization method provided in the present invention can avoid from the process source the possibility that highly toxic impurities such as N-nitrosodimethylamine (NDMA), a valsartan impurity K, and valsartan N-chloride generated in the azide quenching process are introduced into the valsartan methyl ester intermediate, and are further introduced into the valsartan active ingredient, thereby ensuring the valsartan medication safety."
That's the last sentence of that section. Do you see that?
A. Actually, the font is quite small to me. Can you zoom in?
MR. GEDDIS: I'll zoom in on the Chinese.
THE WITNESS: Well, if you zoom in, then half is cut off.
MR. BERNARDO: Is there any way

Page 161

to expand the dialog box so she could actually read the text? This is not...
MR. GEDDIS: It's all been submitted to the link, so she can access it there.
MR. BERNARDO: Dr. Shao, can you point that out to her?
THE WITNESS: I do see such a paragraph.
BY MR. SLATER:
Q. And the inventors who filed this patent, including Jinsheng Lin and Peng Dong and Min Li, correctly referred to NDMA as a highly toxic impurity, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: Well, the document does say so, and the Chinese translation says the same thing.
BY MR. SLATER:
Q. At the very end of that sentence, it also indicated that these changes to the manufacturing process were

Page 162

necessary to ensure the valsartan medication safety, correct?
A. Well, I see the wording in this paragraph, "thereby ensuring the valsartan medication safety."
Q. And you would certainly -- rephrase.
And certainly having NDMA in ZHP's valsartan increases the risk for persons taking those pills to develop cancer. That's why it's called a probable carcinogen, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: That's incorrect. That's completely incorrect.
MR. SLATER: You can take that document down, Chris.
MR. BERNARDO: Adam, whenever you get to a breaking point, we've been going for over an hour.
MR. SLATER: Okay. This is a good time.
MR. BERNARDO: Okay. Thank

Page 163

you.
THE VIDEOGRAPHER: The time right now is 7:43 a.m. We're off the record.
(Whereupon, a recess was taken.)
THE VIDEOGRAPHER: The time right now is 7:58 a.m. We're back on the record.
BY MR. SLATER:
Q. With regard to the NDMA in the valsartan, without us trying to quantify how much risk there was, you would agree with me that the NDMA in the valsartan increased the risk to some level for the people who took those pills to develop cancer, correct?
A. I disagree.
MR. SLATER: Let's put up the Gomm study.
Q. You have this in your binder, correct? You told me that you have it at item number 8 in your binder?
A. I have reviewed this document before, yes.

Page 164

MR. SLATER: Just for the record, Chris, what exhibit number is this?
MR. GEDDIS: 460.
(Whereupon, Exhibit Numbers ZHP-460A and ZHP-460B were marked for identification.)
BY MR. SLATER:
Q. Looking at the first page towards the bottom of the first paragraph on the right-hand column, it states in part, "NDMA is one of the most potent mutagenic carcinogens in animal models and was classified by the International Agency for Research on Cancer (IARC) as probably carcinogenic to humans."
Do you see that?
INTERPRETER SHAO: The interpreter would then read the corresponding paragraph in the Chinese translation.
THE WITNESS: Yes, I see it.
MR. SLATER: Let's go to page 360, Chris. Left-hand column of

Page 165

page 360. Perfect. The Biological background, I'm going to look at the first sentence or two.

Q. Looking now at page 360, there's a heading that says, "Biological background," and it starts out, "NDMA is classified by the IARC as probably carcinogenic (group 2A). It is carcinogenic in the tissues of experimental animal species with metabolism similar to that of human tissues."

Do you see that?

A. Yes, I see it.

MR. SLATER: Let's go back to the first page, Chris.

Q. In the Summary of the study in the Results section, the last sentence states, "A statistically significant association was found, however, between exposure to NDMA-contaminated valsartan and hepatic cancer (adjusted HR 1.16; 95 percent confidence interval [1.03; 1.31])."

Do you see that?

A. Yes, I see it.

Page 166

Q. Looking now at the Conclusion, it says, "These findings suggest that the consumption of NDMA-contaminated valsartan is associated with a slightly increased risk of hepatic cancer."

Do you see that?

A. Yes, I see it.

Q. Coming back to the question I asked you right before we looked at the Gomm study, I asked you, with regard to the NDMA, without us trying to quantify how much risk there was, you would agree with me that the NDMA in the valsartan increased the risk to some level for the people who took those pills to develop cancer?

MR. BERNARDO: Object to the form of the question.

BY MR. SLATER:

Q. This study that you brought with you to the deposition indicates yes, there is an increased risk of liver cancer, correct?

MR. BERNARDO: Object to the form of the question.

Page 167

THE WITNESS: That's incorrect.

BY MR. SLATER:

Q. Are you saying that the Gomm study didn't find a statistically significant increased risk of developing liver cancer?

A. As for the NDMA in valsartan, even though there was some statistical significance, it says here no association was found with the risk of cancer overall.

That is because, apart from the data, they failed to exclude certain factors that would have certain effects. That's written in their conclusion.

So if you only refer to what's said in the front in the Summary, actually that only described the research direction based on IARC's definition.

And in terms of the research content, that is inconsistent with your statement. That's why I say it is incorrect.

Q. The study -- rephrase.

Are you aware that studies like this report the results based on statistical analysis? Yes or no.

Page 168

MR. BERNARDO: Object to the form of the question.

THE WITNESS: I read what's said here. Indeed, this study is based on statistical analysis. However, I also said your conclusion is incorrect.

BY MR. SLATER:

Q. I asked you if the NDMA increased the risk to some level for the people who took those pills to develop cancer.

This study indicates that there was a statistically significant increased risk to develop liver cancer. That's what the finding was in the study with regard to liver cancer, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: No, it's not correct.

BY MR. SLATER:

Q. The words on the page of the study document indicate that the study

Page 169

identified an increased risk of liver cancer.
That is a true statement, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: That's incorrect.
BY MR. SLATER:
Q. So you disagree with the finding documented in the study that there was a statistically significant increased risk for liver cancer, correct?
MR. BERNARDO: Object to the form of the question.
BY MR. SLATER:
Q. Based on your extensive experience as a toxicologist?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: That is completely incorrect.
As I stated very clearly in my prior testimony, I am not a toxicologist, nor am I a pharmacologist.

Page 170

BY MR. SLATER:
Q. Very simple question.
Do you deny that the words on the page of this scientific article indicate that they found a statistically significant increased risk for liver cancer?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: There was no denial in my prior response. I was simply stating the fact that this sentence only described the process of the study.
As for the conclusion of the study, you would have to see the section Conclusion, where it says no association was found with the risk of cancer at all.
So you cannot just focus on one sentence which only described the research process and neglect the overall conclusion.
BY MR. SLATER:
Q. I asked you a question about

Page 171

the finding of liver cancer. Can you please answer with regard to the finding of liver cancer, which is all I asked you about?
A. Sure.
Q. The study found an increased risk for liver cancer, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: That is incorrect, because even though it says here there's a statistically significant slight increased risk of liver cancer as the conclusion, there's no association indicating this causal effect relationship, even though statistically there was some relationship.
So you cannot say that NDMA in valsartan increased the risk of liver cancer.
BY MR. SLATER:
Q. Do you know that all such studies are stated in terms of whether there is a statistical association shown? Are you

Page 172

aware that that's the language of these types of studies?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: As I stated earlier, I was neither a toxicologist nor a pharmacologist.
In order to prepare for this deposition, I worked very hard and did a lot of homework, which includes reviewing this study report and noticed very explicit conclusion.
With that conclusion, I conducted discussion with experts. That's why I said I worked hard for this deposition.
So I disagree with you.
BY MR. SLATER:
Q. Now can you answer my question, please, with a yes or no?
A. In addition, I only reviewed those two study reports. I did not review any other study reports, so I don't know what kind of language they used.

Page 173

Q. When you say you don't know what language they used, you're saying you don't know that these types of studies, that the results are stated in terms of whether or not there's a statistical association?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: Well, I don't know.

BY MR. SLATER:

Q. Do you know what it means for NDMA to be a genotoxic impurity?

A. I agree that NDMA is a genotoxic impurity. However, I do not get your question as to what it means. Can you be more specific?

Q. Do you know what it means for something to be genotoxic?

A. Maybe it has certain effects such as DNA mutagenic.

MR. SLATER: Can you just tell me what that answer was? "DNA" -- did you say "mutagenic"?

Dr. Shao, I'm asking what you

Page 174

said. I didn't hear the word.

INTERPRETER SHAO: Yeah. Yeah. The interpreter did say "mutagenic."

MR. SLATER: Thank you.

Q. The reason that ZHP stopped selling the valsartan with NDMA impurity was because ZHP knew that the potential risk to patients of taking those pills was an unacceptable health risk, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: That is not correct.

MR. SLATER: Let's look at the Gomm study again.

We're on it. Page 360, left-hand column.

Q. Looking again at the Gomm study, which you yourself brought to this deposition, in the middle of the right-hand side under the heading Regulatory and public health implications, the second-to-last sentence says, "The immediate recall of all potentially NDMA-contaminated valsartan drug

Page 175

products by regulatory authorities worldwide was necessary in order to protect public health."

Do you see that?

A. Yes, I see it.

Q. So the authors of the Gomm study thought that it was necessary to recall the NDMA-contaminated valsartan drug products to protect public health, right?

MR. BERNARDO: Object to the form of the question.

BY MR. SLATER:

Q. Let me withdraw the question.

Do you agree that it was necessary to recall the valsartan -- withdrawn, actually.

MR. SLATER: Chris, I'm going to change gears and go to another document, so you can take that down.

Q. You would agree with me that the risk posed by the presence of the NDMA in your company's valsartan was unacceptable, correct?

MR. BERNARDO: Object to the

Page 176

form of the question.

THE WITNESS: I disagree.

BY MR. SLATER:

Q. In terms of the health and safety for patients, the levels of NDMA found in your company's valsartan were not acceptable from a health standpoint, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: It's completely incorrect.

BY MR. SLATER:

Q. From ZHP's perspective, the health risk posed by the levels of NDMA found in ZHP's valsartan was never acceptable, correct?

MR. BERNARDO: Object.

THE WITNESS: It's not correct.

MR. SLATER: Chris, let's go to Exhibit -- previously utilized, Exhibit 127.

(Whereupon, Exhibit Numbers ZHP-127A and ZHP-127B were previously marked for identification.)

Page 177

BY MR. SLATER:
Q. This is an e-mail dated July 13, 2018 written by Hai Wang to someone named Mike Shea.
And he says, "Dear Mike, Please see Valsartan and Valsartan HCZT Recall Notification and Press Release attached. Sincerely apologize for any inconvenience this recall may cause."
And you know who Hai Wang is, correct? Who is that?
A. Of course. I know that Hai Wang is the head of sales in our US company.
MR. SLATER: Let's go now to the attachment to that e-mail, which is Exhibit 128.
(Whereupon, Exhibit Numbers ZHP-128A and ZHP-128B were previously marked for identification.)
BY MR. SLATER:
Q. This is the recall notice referred to by Hai Wang.
Do you see that?
A. I see this document now.

Page 178

Q. And you can see in the middle of the page -- rephrase.
And you can see in the middle of the page, it states, "The exposure to the impurity N-nitrosodimethylamine (NDMA) that was detected in valsartan product line presents an unacceptable carcinogenic risk to the intended patient population."
That's what the press release and information to the customers in the United States stated per this document, correct?
A. That document says so. That did not reflect our company's perspective. This was added by FDA.
MR. SLATER: Chris, let's take that down. And let's go -- I'm going a little out of order of my plan, but let's go to Exhibit 42 if we could, please.
(Whereupon, Exhibit Number ZHP-42 previously marked for identification.)
///

Page 179

BY MR. SLATER:
Q. This document, which I can tell you is dated September 1, 2018, was submitted by ZHP to the FDA and titled "Response to DMF" -- which is Drug Master File -- "Information Request Letter."
Do you see that?
A. Yes, I see it.
MR. SLATER: Chris, let's go, if we could, to page 8 of 33.
Q. This is a table listing testing of over 700 batches of the valsartan produced with the zinc chloride process and the NDMA results in parts per million.
Do you see that?
A. Yes, I see it.
Q. And you can see that these levels range from, in the first column, 76 parts per million down to 37 parts per million at the bottom of that first column; in the next column, lines 420 and 421, levels of 107 and 107.9 parts per million.
Do you see that?
A. Yes, I see it.

Page 180

MR. SLATER: Let's go to page 11 of 33, the top right of that.
Q. You can see more results. I'm just starting at column 517 at the top. 167.3, 188.1, 101.9, 115.5, 164.3, 165.1, 172.3, 164.1, etcetera.
You see these are the levels of the NDMA that was found, and you're aware of that, right?
A. Yes, I have reviewed this document.
MR. SLATER: Okay. Let's take that document down.
Chris, let's go to CHARLESWANG-271, please.
(Whereupon, Exhibit Numbers ZHP-461A and ZHP-461B were marked for identification.)
BY MR. SLATER:
Q. This is an e-mail dated June 10, 2018 from Charles Wang to Min Li.
Are you aware that Charles Wang was a toxicologist who was hired by Min Li to consult for ZHP on the NDMA contamination?

Page 181

A. To my knowledge, I'm aware that Dr. Wang is a toxicologist and a pharmacologist. He was hired by our company to conduct corresponding research after the NDMA incident.

Q. You can see this refers to an attachment, which we'll get to in a moment, which was referred to as "NDMA Safety Assessment and Recommended Limit in Drug Product."

And that's because Charles Wang was hired to advise ZHP as to what would be a reasonable limit for NDMA in the drugs that had been manufactured, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: We did hire Dr. Wang to advise us on the NDMA level standard, because at that time from the regulatory perspective, there was no such standard. So we hired him to see from the regulatory point of view what level should be reasonable.

///

Page 182

BY MR. SLATER:

Q. In fact, ICH M7 had categorized NDMA as part of the cohort of concern, which were chemicals with structures that had extremely high carcinogenic potency, which required a substance-by-substance, case-by-case analysis to establish the levels, and that was something that was understood in ICH at least as of 2013, if not earlier, correct?

MR. BERNARDO: Object to the form of the question.

BY MR. SLATER:

Q. Or do you not know?

A. I am aware of general requirements for the levels of mutagenic -- or genotoxic, rather, impurities, but I do not recall the specific requirements.

Q. Looking now at the text of the e-mail, Charles Wang wrote to Min Li and said, "The attached is draft report for N-nitrosodimethylamine. I can take out the limit of 0.011 parts per million if you are unable to achieve it. See if your client

Page 183

accept the limit recommended based on the maximum intake of NDMA via food or exposure of indoor air. The limit of 0.011 parts per million is calculated based on the EPA recommended limit for underground water, which won't cause the risk to exceeding the tumorigenesis rate of 10e-6 in lifespan of human being."

Do you see what I just read?

A. Yes, I see that through the translation.

MR. SLATER: Let's go now, Chris, to CHARLESWANG-318.

(Whereupon, Exhibit Numbers ZHP-462A and ZHP-462B were marked for identification.)

BY MR. SLATER:

Q. In this document dated June 13, 2018, Charles Wang wrote to Min Li to enclose a revised report with major changes listed below.

And you can see he raised the recommended levels now for interim specification 2 parts per million, long-term

Page 184

specification .625 parts per million.

Do you see that?

A. Yes, I see it.

Q. So in the first report -- rephrase.

When the first report was sent over, Charles Wang said that he can take out the limit he had established if ZHP was unable to achieve a level that low. Then in this revised report, he's raised the levels.

And if you compare those levels to what I showed you on the table in the DMF update, those levels far exceeded all of these levels, correct?

MR. BERNARDO: Object to the form of the question.

MR. SLATER: I'm going to withdraw the question.

BY MR. SLATER:

Q. In the first e-mail on June 10th, Charles Wang offered to take out the limit he had calculated if ZHP couldn't meet it. Now here we are three days later, and he's increasing the limits to be asked

Page 185

for by ZHP.
Do you see that?
A. I've seen both e-mails. After reading both e-mails, my understanding is that this described the process where we were trying to set a standard, because at that time the regulatory authorities hadn't set up any such standard.
Q. At this point ZHP was trying to support the highest level possible in the hope that it could sell the pills that were contaminated with NDMA rather than having to recall all those pills, right?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: That's incorrect.
BY MR. SLATER:
Q. Let's go now to CHARLESWANG-391.
(Whereupon, Exhibit Numbers were marked ZHP-463A and ZHP-463B for identification.)
BY MR. SLATER:
Q. This document is dated June 18,

Page 186

2018, and Charles Wang writes to Min Li, having revising the limit again, and now he has the limit set at 31.2 parts per million.
Do you see that?
A. I see that.
Q. You are aware that the FDA set a limit of .03 parts per million, correct, far lower than the 31.2 that ZHP tried to convince the FDA to accept, right?
MR. BERNARDO: Object to the form of the question.
MR. SLATER: I'll withdraw the question and ask it differently.
BY MR. SLATER:
Q. The FDA ultimately set a limit of .03 parts per million, which was very close to the first recommendation by Charles Wang, in the report where he said he would change the number if ZHP wanted him to because they couldn't achieve that number, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: That's completely

Page 187

incorrect, because in the period of time when this e-mail was written, the regulatory authorities did not come up with any standard for NDMA.
So at that time Dr. Min Li was simply discussing with Dr. Charles Wang what type of limit would be appropriate.
By the way, the eventual standard was not up to ZHP to set. We could only follow the standards set by regulatory authorities such as FDA.
So this only shows the process of discussion as they were trying to find out what limit would be appropriate and acceptable.
BY MR. SLATER:
Q. In terms of what actually happened in June of 2018, the consensus among those scientists responsible for this issue in the United States was that this risk was unacceptable for patients, correct? Meaning the risks posed by the levels of NDMA found in ZHP's valsartan, right?

Page 188

MR. BERNARDO: Object to the form of the question.
THE WITNESS: This is completely incorrect.
BY MR. SLATER:
Q. Well, in fact, the scientists who made the decisions -- well, rephrase.
Well, in fact, the decision was made to set the limit for NDMA at .03 parts per million. That's far lower than the levels that were in ZHP's valsartan, which means the decision was made that the levels in ZHP's valsartan were unacceptable, correct?
MR. BERNARDO: Object to the form of the question.
MR. SLATER: I'm sorry, Dr. Shao. Let me withdraw the question and reask it.
BY MR. SLATER:
Q. The FDA set the level at 0.3 parts per million, which is far lower than the levels that were shown in the ZHP valsartan, which shows that the decision was

Page 189

made that the levels in ZHP's valsartan were unacceptable, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: From the regulatory point of view, ZHP, our company, agrees that to FDA the level of NDMA was unacceptable.
However, we do not agree that the NDMA in ZHP's valsartan would cause harm to the patients and pose carcinogenic risk. We don't agree with that, because that's two different perspectives.
BY MR. SLATER:
Q. It's unacceptable because of the safety risk. That's the definition of "unacceptable," right?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: That's completely incorrect. As I said before, from the regulatory point of view, we have to be very careful and conservative.

Page 190

In that case, the level of NDMA in our valsartan product is unacceptable. However, from the scientific point of view, it doesn't mean that the NDMA in valsartan would pose carcinogenic risk. That's completely different thing.
BY MR. SLATER:
Q. If I understand what you're saying, you're saying from the regulatory perspective, the regulators are very conservative in setting what's unacceptable levels of NDMA because they need to be very protective of people's health, right?
A. Can you repeat your question or rephrase your question? I don't understand your question.
Q. I'll ask it differently.
When you say the levels were unacceptable from a regulatory perspective, that's the reason why the pills could not be sold with those levels of NDMA, correct?
A. Based on the current level set up by FDA, then the answer is yes, we have to

Page 191

follow the requirements of FDA. And the pills with such a level would be unacceptable.
Q. The levels set by the FDA were based on a TD50 analysis, correct?
A. Well, I didn't go into such a detail to find out about how they set up the levels. All I know is that they did set a level.
Q. Do you know what "TD50" means?
A. A little, but I can't say I have a clear understanding. After all, I'm not a toxicologist nor a pharmacologist.
MR. SLATER: Let's go, Chris, to CHARLESWANG-267, please.
(Whereupon, Exhibit Numbers ZHP-464A and ZHP-464B were marked for identification.)
BY MR. SLATER:
Q. The e-mail at the bottom part of this page was sent by Min Li to Charles Wang on June 21, 2018, regarding a paper on NDMA high-low dose prediction.
And he says to Charles Wang,

Page 192

"Hi, Charles. I need your brain again to take a quick look of this paper. It seems to me that using high dose experiments may not be able to predict low dose results. My goal is trying to demonstrate that a previously reported TD50 for NDMA as cited by our client in her report may not be accurate.
"I will talk to you later today."
And then up above you say, "This is the Reply from the authors of the paper I sent to you below. It may also help you to evaluate."
Do you see that?
A. I see it.
MR. SLATER: Let's go now to CHARLESWANG-430.
Q. Charles Wang responds to Min Li on June 22, 2018, and says, "Hi Min, the paper and Reply that you sent to me were published in early '90s. They are outdated. We should obtain the data from the current publication, especially those published on Regulatory Authority website, EPA, FDA, NIH,

Page 193

WHO, etc. The TD50 for NDMA listed on NIH website are 0.0959 in rats and 0.189 in mice" -- and it gives a link, "NITROSODIMETHYLAMINE.html and in 2016 EFSA Journal 2016 (see attached)." So there's this link and the citation.

He then says, "NDMA is a well known carcinogen in animals and probable carcinogen in human based on EPA classification (Class 2A).

"I suggest Huahai to hire a carcinogenicity expert consultant to perform the analysis, who knows risk assessment of carcinogen and kept updated in regulatory guideline and standards in this field. If needed, I can recommend a couple to you for consideration."

Do you see that that was the response by Charles Wang to Min Li, who had in the prior e-mail sent a paper where he was trying to refute the use of high-dose animal experiments to predict low-dose results?

You see that, correct?

MR. BERNARDO: Object to the

Page 194

form of the question.

THE WITNESS: I do see what the e-mail says. However, your statement fails to reflect the meaning or intention of this e-mail.

MR. BERNARDO: Adam, when you hit a breaking point, we'd like a break.

MR. SLATER: I'll take a break now.

MR. BERNARDO: Great. Thank you.

THE VIDEOGRAPHER: The time right now is 9:15 a.m. We're off the record.

(Whereupon, a recess was taken.)

THE VIDEOGRAPHER: The time right now is 9:28 a.m. We're back on the record.

BY MR. SLATER:

Q. You just said you disagreed with my question. Are you now saying that you do understand the TD50 analysis that you

Page 195

said before you did not truly understand?

A. Maybe you misunderstood me. I already told you that I know a little bit about TD50, but I do not know the specifics. After all, I'm not a toxicologist nor a pharmacologist.

In general, I understand when setting the limit, TD50 is just to be used to calculate the acceptable limit. That's all I know.

Q. The response by Charles Wang to Min Li that we just read a moment ago confirming that NDMA is a well-known carcinogen in animals and probable carcinogen in humans based on EPA classification is consistent with the scientific consensus that ingesting NDMA as a contaminant of valsartan posed a health risk to those people that took the pills, correct?

A. That is incorrect.

MR. SLATER: Let's go to CHARLESWANG-447, please.

Q. Looking at the very bottom of this first page, which goes over to the

Page 196

second page, let's start with that e-mail sent by Charles Wang on July 5, 2018 to Jim MacDonald.

MR. SLATER: And you can scroll over to the top of the second page, please, Chris?

Q. The e-mail from Charles Wang to Jim MacDonald states, "Hi Jim, Nice to hear from you. Hope everything is going well. Sorry to disturb you during your vacation. My friend's company will have a face-to-face meeting with FDA to" -- it says, "debit if they should recall their product in US market next Thursday, and likes to get some advice from people like you quickly." And I want to stop there.

You recall that in the prior e-mail, Charles Wang had suggested to Min Li to hire a carcinogenicity expert consultant to perform the analysis who knows risk assessment of a carcinogen and kept updated in the regulatory guideline and standards in this field, and you can see this is an e-mail written to somebody with that background.

Page 197

Do you see that?
A. I see this.
Q. The e-mail continues in the second paragraph, "Not sure if you heard, Huahai Pharma Group, one of the largest generic drug company in China with a branch in US (Cranberry, New Jersey). Li knows their US CEO as well. Huahai has a product in US market with the maximum daily dose of 320 milligrams, which recently was found containing high nitrosodimethylamine (NDMA, not know exactly how much but around 30 parts per million). Their client in European Union said it should be at 0.33 parts per million, based on TD50 calculation. They would like to know if they can argue to set limit higher based on NDMA is considered a Class 2A carcinogen (limit at threshold of toxicological" -- I'm blanking on the rest of it, but "TTC of 1.5 ug per day) and the longest duration of human exposure in US will be less than three years.
"Let me know if your company can help. I will ask them to contact you

Page 198

directly and send you more details."
Do you see that?
A. I see it. I see it.
Q. Just to make it clear, I had forgotten TTC for a moment. That's threshold of toxicological concern.
Are you aware of that?
A. Like TD50, I know a little bit about TTC, but I do not know the specifics. All I know is that in general, TD50 or TTC will be used to calculate the acceptable limit. Actually, there are quite a few ways to make use of those data.
Q. Looking at a few things stated in this e-mail, Charles Wang called it "high nitrosodimethylamine" and said he thought it was around 30 parts per million.
Do you see that?
A. Yes, I see it.
Q. And you recall from the prior e-mails we went through that after starting at a level of .0111 parts per million, Charles Wang actually went all the way up to 31.2 parts per million, which is just a

Page 199

little bit higher than what he thought was the levels being seen in the valsartan of 30 parts per million.
Do you remember he went up to 31.2?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: I see both e-mails, and you're correct. The limit was indeed increased to 31.2.
However, I would point out that your understanding or interpretation of all those e-mails are completely wrong.
As seeing this e-mail, it did say that the longest duration of human exposure in the US would be less than three years. So when they do the calculation, they're calculating the total amount and they are calculating using a different data from different angles; therefore, I'm unfamiliar with what Dr. Wang was going through at this time.

Page 200

In order to calculate a reasonable acceptable limit, they have to calculate based on the long-term exposure and short-term exposure.
For example, at that time our valsartan was not in the US market for three years yet, so it's not like they tried to increase the limit on purpose so that we could avoid the recall.
It was, rather, a process where they would discuss with FDA regarding the limit considering the time of our valsartan in the market.
So this, rather, is the process to set the limit. After all, eventually it was up to FDA to set the limit and make the approval.
BY MR. SLATER:
Q. My question was simply to confirm that the level of 31.2 parts per million which Charles Wang increased up to after starting at .0111 parts per million was just a little higher than the 30 parts per million that he believed was the levels in

Page 201

ZHP's valsartan.
That's a correct statement, correct?
MR. BERNARDO: Object to the form of the question.
INTERPRETER SHAO: The interpreter is asked to repeat the rendition.
THE WITNESS: That's incorrect. That is completely incorrect.
BY MR. SLATER:
Q. Charles Wang didn't increase the levels in his reports from .0111 parts per million up to 31.2 parts per million? I thought we just went through that in the documents.
Are you disagreeing that his level went up to 31.2?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: As stated in my prior testimony, your understanding or interpretation of all these e-mails were not completely correct.

Page 202

I remember the original level of .01 ppm was based on the long-term level of the -- or long-term exposure, rather, to the groundwater. But the limit has to be associated with the duration of exposure.
So over here they were talking about the exposure time of three years, which is much shorter. So they were wondering whether the limit can be increased to 31.2 ppm.
Once again, the limit has to be associated with the duration of exposure in terms of years. And what we see here is actually the scientific discussion period where theoretically they want to see how much the limit can go to.
It's not like, oh, they already know -- or he already knew, rather, that ZHP's valsartan has about 30 ppms NDMA, so he would increase the limit to 31.2, just a little bit above it.
We're looking at a theoretical

Page 203

discussion process here.
BY MR. SLATER:
Q. You don't understand that they were going to meet with the FDA to talk about the limit going forward, and that was going to be the determiner of whether they could continue to sell the pills that they had manufactured contaminated with NDMA?
Do you not understand that?
MR. BERNARDO: Object to the form of the question. Sorry.
THE WITNESS: As seen in this e-mail, he was simply trying to collect some information and data from the expert so that such data can be used in the face-to-face meeting with FDA.
As you know, our company does not conduct any toxicological or pharmacological studies; therefore, we have to rely on experts for their information.
One thing is for sure, is that whether valsartan could be sold or had

Page 204

to be recalled at that time was not decided by ZHP. Rather, it would be up to FDA to make the approval, not ZHP.
So we were trying to take multiple approaches to collect the information and data so that we could conduct a meaningful discussion face-to-face with FDA.
BY MR. SLATER:
Q. You see that Charles Wang states that ZHP's client in EU, European Union, said that the limit should be at 0.3 parts per million based on TD calculation. And as you're aware, that's the level the FDA actually adopted, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: The e-mail does say that the client in the EU said it should be added .3 ppm based on TD50 calculation.
However, my understanding is that is also based on long-term

Page 205

exposure with no limit of a time period.

So we're talking about different standards right here.

MR. SLATER: Let's go to the first page of the e-mail.

Q. Now let's look at Jim MacDonald's response, Jim MacDonald from Synergy Partners R&D Solutions, who is the carcinogenicity expert consultant that Charles Wang reached out to after asking for clearance from Min Li to do so.

He writes, "Charles, I'm afraid I can't be of much help in this case particularly on this time scale. NDMA (or dimethylnitrosamine) is a pretty well-known toxin and animal carcinogen."

I'm going to stop there.

Do you see where I'm reading?

A. I do see what's written here. However, I do not know what this person is -- or who this person is, rather, because I did not do any study on it.

Q. You said you interviewed

Page 206

Charles Wang as part of your preparation for this deposition, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: That's incorrect. I never mentioned his name. I did say I read Dr. Wang's report instead.

BY MR. SLATER:

Q. Continuing in the e-mail a little further down from where I just read, Jim MacDonald states, "The body of evidence on this suggests pretty clearly that this is a likely human carcinogen at sufficient exposures. The argument that the company would have to make to keep this product on the market will be very difficult with this profile. I'm not exactly sure where one would begin given the very high levels you think they are seeing."

And just to be clear, the "very high levels" he's referring to are what Charles Wang had said in the prior e-mail, around 30 parts per million.

That was the level he quoted,

Page 207

correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: I don't quite understand your question, because I don't see your quotation in this e-mail. I cannot see the English version, so I can only rely on the Chinese translation.

BY MR. SLATER:

Q. And in fact, 30 parts per million, which was the level quoted by Charles Wang in the prior e-mail that we went through, would be at the low end of what I showed you on that table in the DMF update that we went through, where I showed you those many results that went up close to 200 parts per million and many over 100 parts per million.

Remember we saw that?

A. Yes, I did see the result of NDMA.

Q. Jim MacDonald then says a little further down, "I expect this is not

Page 208

what they would want to hear but, unless there is a compelling reason to leave this product on the market (for example, only product available to treat a serious, life-threatening disease), I would expect the FDA would ask for a recall."

And then a little further down he says, "These things are always very difficult to predict - but this is not a good position for this product in my view."

Do you see that?

A. I heard the translation, but I can't read English.

Q. Going to the top of the page, Charles Wang wrote to Jim MacDonald a few weeks later, July 17, 2018, and said, "Hi Jim, You may have seen this." And it's a link to the announcement of the recall, I represent to you, and he says, "It is exactly like you expected, and I agreed with your call."

You see that, correct?

A. I don't know -- I don't know where it is in this document. I can't read

Page 209

English, but I heard the Chinese translation.
MR. SLATER: All right, Chris. Let's go now -- take that down, and let's go to ZHP "to whom it may concern," which I believe is ZHP00374340. Let's start with that and show that to the witness.
(Whereupon, Exhibit Numbers ZHP-465A and ZHP-465B were marked for identification.)
BY MR. SLATER:
Q. This document states about halfway down the first page, "This information package, provided to Huahai's customers who have purchased Valsartan DS (CEP 2010-072), consists of the following four parts:
"Background of the event;
"Root cause investigation;
"Risk assessment based on toxicological evaluation;
"Recommended actions and future plan."
And this would have been

Page 210

something that would have been sent to the customers who were purchasing ZHP's valsartan, correct?
A. Based on the translation, I would like to think so.
MR. SLATER: Now, Chris, let's go to -- now that we've seen this document, I want to pull up a version of it that was actually produced by Teva, one of those customers who received it, and it's TEVA-MDL2875-00783229.
Q. And I can represent to you this is the same document we just looked at. It was the one that was produced by Teva as they had received it.
MR. SLATER: And let's go, if we could, to page 14 -- actually, page 13 out of 17.
Q. Looking now at page 13, there's a heading towards the bottom of the page, "Section 3.1.5, IARC Classification and Rationale for Proposed Daily Limits Based on Lifetime and One to Ten Years of Exposure."

Page 211

And if we flip over to the next page to the conclusion of that page in terms of what customers of ZHP were being told --
MR. SLATER: Let's go to page 14. Please go to page 14.
MR. GEDDIS: This is page 14, Adam.
MR. SLATER: Oh, okay. Now it is.
BY MR. SLATER:
Q. Continuing, we see that ZHP was advocating here for a limit of 31.2 parts per million. It says, "For the maximum dose of patients that take valsartan drug products at the maximum daily dose of 320 milligrams for one to ten years."
Do you see that?
MR. BERNARDO: Object to the form of the question.
Can somebody put their phone on mute?
MR. WILLIAMSON: I think, Ms. Kapke, that's your microphone.
MR. SLATER: Yeah, I'm just

Page 212

going to clean this up. I'm going to start over because we had a couple little glitches there.
Q. So starting on page 13 where we started, Section 3.1.5 is titled "IARC Classification and Rationale for Proposed Daily Limits Based on Lifetime and One to Ten Years of Exposure."
And if we go over to the next page, this section concludes with the statement, "Therefore, the limit of NDMA in valsartan drug products can be set at 31.2 parts per million for the maximum dose" -- it gives a calculation -- "if patients take valsartan drug products at the maximum daily dose of 320 milligrams for one to ten years."
So you can see that ZHP included in this recommendation to its customers, including Teva, a 31.2 parts per million acceptable limit.
Do you see that?
MR. BERNARDO: Object to the form of the question.

Page 213

THE WITNESS: I heard the Chinese translation. I cannot read English here, but I did see the numbers you mentioned in your question.

As I said earlier, we looked at the e-mails among Dr. Wang, Min Li, and the so-called expert. I could tell that they were in the process of discussing the limit setting.

What we see here is only a letter to our client. Once again, the limit is not set by ZHP; rather, it's set by FDA. That's why we needed to bring all the information data to our face-to-face meeting with FDA.

MR. SLATER: Let's go back to the prior page, page 13. Beginning of that section.

MR. BERNARDO: Adam, I'm sorry to interrupt --

MR. GEDDIS: What page, Adam?

MR. SLATER: Page 13.

MR. BERNARDO: I thought she

Page 214

asked if there was a Chinese version, maybe --

MR. SLATER: Yes, it's been sitting in the exhibit folder.

MR. BERNARDO: Dr. Shao, would you just remind Ms. Ge that she has access to the Chinese version so she can look at it if she'd like?

INTERPRETER SHAO: Could the counsel remind the witness of the exhibit number?

MR. SLATER: Chris, what's the exhibit number?

MR. GEDDIS: 466.

THE WITNESS: I can't find this document.

MR. GEDDIS: You might have to refresh the window.

MR. SLATER: Why don't you do that. Let's do whatever we need to do to get it for her.

THE WITNESS: Well, it seems like I found the link, I clicked, and they were asking for password. When I

Page 215

tried to click on the link, they were asking for a password.

Now I see. What's the number again?

MR. SLATER: 466. 466B.

(Whereupon, Exhibit Numbers ZHP-466A and ZHP-466B were marked for identification.)

THE WITNESS: Hold on. Let me download this document first.

Now I can open it.

BY MR. SLATER:

Q. Can't open it, or can?

A. I am able to open it.

Q. Great. Go to page 13, please.

A. I just want to confirm whether this document is a machine-translated file --

Q. Yes.

A. -- because looking at the format, it looks weird.

Q. Yes.

Looking at page 13, the last heading that we were reading underneath, in terms of the method that was followed to

Page 216

calculate that 31.2 parts per million, this states, "Per ZHP, in IARC (International Agency for Research on Cancer, a World Health Organization organization) classification, NDMA is classified as Class 2A. Hence, the daily intake of NDMA can be controlled at or below the acceptable limit (appropriate threshold of toxicological concern)," and it gives that number for lifetime exposure "according to ICH guideline M7(R1)." So that was part of the rationale for this statement.

Do you see that?

A. Well, the Chinese translation of this document is all scrambled and illegible. But I did hear the Chinese translation.

MR. SLATER: Now, I just want to flip back for one moment to page 12.

Q. At the bottom of the page you'll see a table, and under the table it refers to a World Health Organization report. A table from the report is shown above, and then just at the bottom of the page there's a

Page 217

citation to that report from the World Health Organization in 2002.

Do you see that at the bottom of that page, page 12?

A. Yeah, I see that. However, the translation is really weird here.

MR. SLATER: Let's go now -- let's take that document down, and let's go to TEVA-MDL2875-00540386, please.

(Whereupon, Exhibit Number ZHP-467A and ZHP-467B were marked for identification.)

BY MR. SLATER:

Q. Starting right at the top of the page, there's an e-mail from Raphael Nudelman, and we can see who he is down below in the signature line; he's a Ph.D., ERT director of chemical and computational toxicology at Teva.

And he's writing to somebody at Teva regarding "Urgent Valsartan Safety Assessment Request."

Do you see what I'm talking

Page 218

about? Do you see the e-mail in front of you?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: I see this e-mail because I heard the Chinese translation. I can tell this is an internal communication within Teva.

BY MR. SLATER:

Q. Looking now at the second paragraph, Dr. Nudelman says, "I indeed had considerable reservations to the Huahai assessment which concluded with a large difference in the overall permitted daily exposure of NDMA. Huahai's understanding of the IARC categories, their incorrect use of the ICH M7 categories, and incorrect use of the LTL, brings me to the conclusion that their assessment was totally unacceptable."

Do you see that?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: Well, the interpreter kept going, so I just

Page 219

heard the translation.

BY MR. SLATER:

Q. A little further down it says, "The fact that NDMA was present in Valsartan since 2012 cannot be used as a justification for its safety. Carcinogenicity can still develop in patients who received this drug containing NDMA in the past 6 years."

So you see that Dr. Nudelman from Teva thought that there is an increased risk of cancer to people who took valsartan manufactured with ZHP's contaminated API.

You see that, right?

MR. BERNARDO: Object to the form of the question.

MS. LANGTON: Join.

THE WITNESS: Well, I just heard the interpreter's Chinese translation even though I could not tell what's written here.

My understanding to the e-mail is that this is an internal communication within Teva as to who this person is. Even though it has

Page 220

some description here, it's still unclear to me.

Furthermore, I do not know where you could find the supportive data in human to support his statement about a carcinogen. I have talked with quite a few experts, and they were telling me there was not data in humans to support that it was a human carcinogen.

Since this is merely an internal communication within Teva, I would not make any comment on the content of this e-mail.

BY MR. SLATER:

Q. The so-called experts you spoke to were hired and paid by ZHP. Do I understand that correctly?

A. I don't think your interpretation is correct.

Q. Looking at the e-mail a little further -- I'll start over.

Looking a little further down, two more paragraphs, Dr. Nudelman, the

Page 221

director of chemical and computational toxicology at Teva, says, "I fully agree that hypertension treatment is chronic and the less-than-lifetime (LTL) argument cannot be used in this case."

So that would disagree with the idea that you could have different levels based on the assumption that somebody would use the drug for a short period of time.

Do you understand that?

MR. BERNARDO: Object to the form of the question.

MS. LANGTON: Join.

THE WITNESS: Through the Chinese translation, I understand what you are talking about.

My understanding of this paragraph is that they were still in discussion on the limit setting for NDMA in valsartan, as to how high the limit would be, and it's up to the FDA and EU's regulatory authorities to set.

Before they set such limits,

Page 222

they were still talking about it themselves based on their knowledge and understanding. That's quite common for such complications.

My understanding is that it is up for the EU's regulatory authority to set the limit in Europe. If it's in the US, then it is up to FDA to approve such limits.

Before they approve such limits, everyone was still discussing among themselves based on their knowledge and understanding, but eventually whatever limit approved by FDA would be the final limit.

BY MR. SLATER:

Q. If ZHP advocated for unreasonably high levels in the hope of being able to sell more of the pills and make more money, that would have been completely inappropriate and wrong, right?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: I believe your

Page 223

question is very weird, because ZHP never tried to sell more pills and make more money.

That is why, once we learned about the NDMA in valsartan, we immediately approached FDA and EU. We never hoped that we would sell more valsartan.

As for the e-mails that we just looked at back and forth among those people, we were trying to get help from experts and get their advice, information, and data so that we could take all these to the FDA for communication.

We would not take any action until those actions would be approved by FDA. Whatever work we conduct has to be conformed to FDA's requirement.

MR. SLATER: Let's go now to TEVA-00068399.

MR. BERNARDO: Break, Adam?

MR. SLATER: I'd like to finish this line with this document, if I

Page 224

could, please.

MR. BERNARDO: Sure.

(Whereupon, Exhibit Numbers ZHP-468A and ZHP-468B were marked for identification.)

BY MR. SLATER:

Q. This is the toxicological assessment for NDMA prepared by Dr. Nudelman at Teva. And you can see towards the bottom is the Assessment, where he says in the middle of that section, "The ICH M7(R1) guideline for mutagenic impurities considers compounds which are mutagenic carcinogens as Class 1 substances that need to be controlled according to compound-specific accepted limits. The M7 guideline explains that this compound-specific accepted limit is linearly extrapolated from the TD50 value."

And then in the next line he states, "For the highest dose of Valsartan (320 milligrams per day) the limit for NDMA calculates to 0.57 parts per million."

Do you see that?

MR. BERNARDO: Object to the

Page 225

form of the question.
THE WITNESS: I heard the translation, and I also saw some of the numbers.
BY MR. SLATER:
Q. When you were being prepared to testify in this deposition on the increased risk questions, you were given some information and spoke to paid experts for ZHP, but you weren't shown these documents that I'm showing you now, right?
MR. BERNARDO: Object to the form of the question.
BY MR. SLATER:
Q. I'll ask it differently.
When you were being prepared for this deposition, were you shown these documents where they reacted to the positions that ZHP took at the time in 2018?
I just want to know, were you given this information to help prepare yourself for this deposition?
MR. BERNARDO: Object to the form of the question.

Page 226

THE WITNESS: My first point is I did not read any of the internal complication documents within Teva.
My second point is that, indeed, the -- my second point is that for this preparation of the deposition, I did a lot of preparation work.
My third point is that I don't believe I need to review the internal communication documents within Teva, because at that time in setting the limits -- or acceptable limit, that is, for the NDMA in valsartan, people were discussing with themselves. They were also consulting with external experts.
But eventually it's not up to those enterprises to set the limit. Whatever limit has to be approved by FDA, which they did. As you can see later, FDA and EU set the limit and made it public in their public announcement.

Page 227

So for us, we have to follow FDA or EU's GMP official requirement in order to conduct our work.
To me, such internal technical communication is very normal. I don't believe I need to review any documents within Teva. All I need to do is to follow FDA for the requirements they set.
MR. SLATER: Rick, did you say you wanted to take a break for a couple minutes?
MR. BERNARDO: Yes, please.
MR. SLATER: Okay.
THE VIDEOGRAPHER: The time right now is 10:48 a.m. We're off the record.
(Whereupon, a recess was taken.)
THE VIDEOGRAPHER: The time right now is 11:02 a.m. We're back on the record.
MR. SLATER: All right. Chris, can we put the information package to

Page 228

the customers back up and go to page 12, where we were before?
BY MR. SLATER:
Q. You see the table that is shown there, and it says, "According to a World Health Organization report, a table of the report is shown above. A reasonable worst-case estimation of daily intake of NDMA from different sources by general population at different age groups are listed in the table above." And then it gives an example, and it cites to a World Health Organization study from 2002.
Have you actually looked at that World Health Organization document that is cited by ZHP in this information packet to its customers?
A. Are you asking me whether I reviewed this document generated by Huahai, or I reviewed the WHO report cited by this document?
Q. The WHO report from 2002.
A. No, not for this one.
Q. Okay. Let's go now to the

Page 229

World Health Organization document, ZHP-321.
(Whereupon, Exhibit Number ZHP-321, previously marked for identification.)
BY MR. SLATER:
Q. This is the World Health Organization report from 2002 titled "N-nitrosodimethylamine," and that is what is cited in that information packet to ZHP's customers.
And what I'd like to do now is turn to page 13, where we can then see that it's the same table that we just saw in the information packet to the customers.
There it is.
Do you see that that's the same table, "Reasonable worst-case estimates of daily intake of NDMA"?
A. I see the table, and I also see numbers in this table, but I'm not sure I understand what it says in that table.
MR. SLATER: Let's go now to page 23. Actually, let's go to page 22 to start.

Page 230

Q. You can see on page 22 in the bottom right is a heading called "Carcinogenicity."
MR. SLATER: And let's now continue over to the next page, to the end of that section at the top right-hand corner of page 23.
Q. And this document states, "Therefore, owing to the considerable evidence of carcinogenicity of NDMA in laboratory species, evidence of direct interaction with DNA consistent with tumour formation, and the apparent lack of qualitative species-specific differences in the metabolism of this substance, NDMA is highly likely to be carcinogenic to humans."
That language I've just read was not included in what was sent in the information packet to ZHP's customers. Only that table that we showed a few pages earlier was shown to them, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: I saw both this

Page 231

article and the letter to our clients. However, I do not read English, so I'm not sure whether the paragraph you just read was included in the letter to the customers.
Seems to me that they are just referring to experiments, laboratory animals, regarding NDMA. So I'm not sure whether this paragraph was included in that letter. After all, I cannot read English.
MR. SLATER: Let's go back to page 21.
Q. This shows that in section 9, "Effects on Humans," that, in fact, there was analysis of studies having to do with human intake of NDMA.
So you had just wondered if human studies were considered, and I'm showing that to you.
Do you see that?
MR. BERNARDO: Object to the form of the question.
Is there a translated version

Page 232

of this?
THE WITNESS: I cannot read this article because they are in English. I can figure the number 9, but I'm not sure whether that's referring to the effects on human.
BY MR. SLATER:
Q. There is a Chinese translation, as with every one of the documents that we've used in this deposition. So you've always had the opportunity to access that in the same place.
MR. BERNARDO: I'll note for the record that with respect to the machine, the translator has observed that most, if not all, of the Chinese translations are unintelligible and confusing.
MR. SLATER: I'm not going to argue the point with you, Counsel.
MR. BERNARDO: I'm not asking you to.
MR. SLATER: You asked if there was a translation; I said yes.

MR. BERNARDO: You said more than that.
BY MR. SLATER:
Q. In preparing for this deposition, am I correct you were not aware that ZHP had in its possession this study, which concluded that NDMA is highly likely to be carcinogenic to humans? Yes or no.
MR. BERNARDO: Object to the form of the question.
THE WITNESS: That's incorrect.
BY MR. SLATER:
Q. So you did review this report?
A. No. Because what's written here is all in English, I can't understand it.
Q. It's a very simple question.
Did you have this report provided to you, either in English or in Mandarin, as part of your preparation for this deposition? Yes or no.
MR. BERNARDO: Object to the form of the question.
THE WITNESS: During the

preparation, I have reviewed many documents.
And I don't think I need to review this document because in terms of preparation, what I have done is sufficient.
BY MR. SLATER:
Q. It was sufficient for you to be prepared by paid experts for ZHP who were paid to dispute the increased risk, as opposed to reading a report from the World Health Organization indicating that NDMA is highly likely to be carcinogenic to humans? Is that what you're telling me? Yes or no.
MR. BERNARDO: Object to the form of the question.
THE WITNESS: That's totally incorrect.
BY MR. SLATER:
Q. Were you aware when you were being prepared for this deposition that this World Health Organization report from 2002 was in ZHP's files? Yes or no.
A. I didn't verify that. However,

even after they mentioned this report, I read the conclusion from IARC. So I don't think I need to read many documents, because IARC's conclusion is very clear to me.
Q. The IARC conclusion that NDMA is a probable human carcinogen, that's what you're referring to, correct?
A. In IARC's conclusion, it was written very clearly that out of practical concerns, even though there was no human data, out of the practical concern for the high-dose scenario, NDMA is regarded as a probable human carcinogen.
Q. The IARC monograph actually doesn't say anything about high dose; it just says it's a probable human carcinogen, actually, right?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: That's incorrect. IARC did mention that so far they still don't have any human data. They do have, however, some data of high-dose animals.

BY MR. SLATER:
Q. Are you aware that it would be unethical to study the effects of NDMA on humans because of the strong evidence of carcinogenicity? Yes or no, are you aware of that?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: I don't get your question. Are you referring to imposing NDMA onto human beings?
BY MR. SLATER:
Q. Are you aware that it would be unethical to deliberately give NDMA to humans in order to study whether and to what extent it would cause cancer in humans because of the strong evidence of it being a mutagenic, genotoxic carcinogen?
Are you aware of that? Yes or no.
MR. BERNARDO: Object to the form of the question.
THE WITNESS: As I told you before, I am not a toxicologist nor a

Page 237

pharmacologist. All I have to do is to rely on the agencies, well-known agencies and experts.

As for the human data, I don't know how they would have conducted their analysis, whether they used any human data or not.

However, I also don't know how they did not -- how they conducted statistical analysis on that. I didn't realize that I have to prepare to such details for this deposition.

MR. SLATER: I have no further questions at this time. I'll hand the witness -- pass the witness, I guess -- to defense counsel.

MR. BERNARDO: Just give me a couple minutes.

THE VIDEOGRAPHER: The time right now is 11:26 a.m. We're off the record.

(Whereupon, a recess was taken.)

THE VIDEOGRAPHER: The time

Page 238

right now is 11:32 a.m. We're back on the record.

EXAMINATION

BY MR. BERNARDO:

Q. Good morning, Ms. Ge. We obviously know each other, but let me introduce myself for the record. I'm Richard Bernardo. I'm counsel for ZHP.

Thank you for taking the time to talk with Mr. Slater and me as well. I know you had to travel a distance to participate in this deposition.

Ms. Ge, I just want to talk to you a little bit about your background and just make sure we clarify what might be some confusion through some earlier questions.

Tell the jury what your education is, Ms. Ge.

A. Of course. Good morning, everyone. My name is Jucai Ge. I am currently the quality assurance director for API in ZHP.

As for my educational background, in 2002 I graduated from Tianjin

Page 239

Institute of Technology with a major in pharmacology, and I joined ZHP after there, after then, after that time. I have been around ZHP ever since.

Q. Thank you, Ms. Ge.

And what year did you graduate with a major in pharmacology?

A. 2000.

Q. And so you've been at ZHP since approximately 2000?

A. That is correct. Time flies. I feel that as if yesterday, you know, I was still on campus, and suddenly more than two decades have already passed.

Q. 22 years is a long time.

Ms. Ge, would you help the jury understand just briefly what a quality assurance director does? What are your responsibilities?

A. As a director of quality assurance, in general, I'm in charge of the construction or establishment, maintenance of the quality system, work with any GMP inspections.

Page 240

Also, right now I am in charge of the supplier qualification.

At the same time, I'm also in charge of setting up the quality system for one of the subsidiary companies of ZHP.

Q. So 22 years at ZHP, Ms. Ge. Fair to say you like working at ZHP?

MR. SLATER: Objection.

You can answer.

THE WITNESS: Of course. Otherwise, who would stay in the same company for over 20 years?

The reason why I've been working with ZHP is because I like the working environment here, which is very good. Everyone around me is very nice, they work hard, and they've been very careful and diligent.

Also, it's -- basically, a lot of people who either joined the company at the same time as I did or joined the company before I did are even still with ZHP, so they're being with ZHP for over 20 years or close to

Page 241

20 years. So after all, the work environment is very good here.
BY MR. BERNARDO:
Q. Do you feel you also work hard and diligently, given your responsibilities as the director of quality assurance?
MR. SLATER: Objection.
You can answer.
THE WITNESS: Of course. As I said, in such a working environment, everyone is working hard and seriously and diligently. We all work together trying to fulfill our responsibilities.
That is just definitely necessary because, after all, ZHP doesn't belong to one person; it belongs to all of us. That's why I think for this working environment, everyone is working hard.
BY MR. BERNARDO:
Q. Mr. Slater asked you a number of questions suggesting that ZHP knew that NDMA formed in valsartan as early as the summer of 2017, but didn't disclose that

Page 242

information.
Do you recall those questions?
MR. SLATER: Objection.
You can answer.
THE WITNESS: We had a lot of communications on this line of questions. I don't know whether he got my feedback.
To the best of my knowledge and based on my 20 years of experience in ZHP, I can respond very responsively that before July 2017, or even before June 2018 when Novartis suggested to us that there might be NDMA in valsartan, nobody at ZHP knew there was NDMA in valsartan. I just want to clarify that.
BY MR. BERNARDO:
Q. How do you know that, Ms. Ge?
A. That is because before June 2018 there was not an analytical method that would identify NDMA in valsartan.
That is one of the most important reasons. If you don't have the

Page 243

right analytical method, how could you identify NDMA in a test.
Q. What about Jinsheng Lin, the author of the document that you spent a fair amount of time discussing with Mr. Slater? Do you have an understanding whether he in particular knew that NDMA formed in valsartan in 2017?
MR. SLATER: Objection.
You can answer.
THE WITNESS: That is impossible, because I asked him and he told me that at that time he was not aware of the existence of NDMA in valsartan.
He only -- his understanding of the impurity was only restricted to the knowledge he got from the patent that was attached to that e-mail. At that time, he was not in charge of this valsartan product.
BY MR. BERNARDO:
Q. Let me break that down a little bit, Ms. Ge, in following up on some of

Page 244

Mr. Slater's questions about Mr. Lin's knowledge.
So before he wrote the memo, what is your knowledge of the information that was available regarding NDMA, if anything?
A. I communicated with him and had a discussion with him regarding this topic.
According to him, in general, NDMA was a common, natural N-nitroso compound. It's a very common compound. And he was not aware that NDMA was in valsartan. That was his general knowledge at that time.
Q. Thank you.
You talked quite a bit in your testimony about a patent application.
Do you remember that?
A. Well, yes.
Q. And do you have -- and as I'm recalling your testimony, it was that Mr. Lin had this patent application before he wrote his July 27, 2017 memo that you discussed, is that correct?
MR. SLATER: Objection.

Page 245

You can answer.
THE WITNESS: I communicated with Jinsheng Lin on this topic, and I also provided my response, being the prior testimony.
At that time when he was writing the e-mail, either it was several hours prior to that or sometime on the same day. Whichever the case, he could not recall, he was trying to make a comparison about in toxicology; therefore, he conducted an online search and found this patent.
BY MR. BERNARDO:
Q. And by "this patent," Ms. Ge, you're referring to the one that he attached to the July 27, 2017 memo?
A. That is correct.
Q. So he did some online research, found this patent application that he discussed.
Let's talk about that. Does the patent application anywhere discuss NDMA?
MR. SLATER: Objection.

Page 246

You can answer.
THE WITNESS: NDMA was not discussed from cover to cover in the entirety of this patent.
BY MR. BERNARDO:
Q. So what does the patent application discuss, Ms. Ge?
A. That patent discussed Impurity K in valsartan.
Q. And what is Impurity K?
A. Impurity K is also one of the N-nitroso compounds.
Q. Do you recall that Mr. Slater raised the patent referred to nitroso compounds, plural?
Do you recall that?
A. Yes, he did. However, I also told him that Impurity K is one of the N-nitroso compounds.
Q. Now, do you have an understanding, Ms. Ge, about how many known nitroso compounds there are?
A. As I told Mr. Slater this morning, there were thousands, if not tens of

Page 247

thousands, of nitroso compounds in the world. However, this patent only mentioned Impurity K.
Q. I want to go back to the July 27, 2017 memo.
Now, you testified, Ms. Ge, that you took steps to investigate what Dr. Lin was trying to communicate in this memo, is that correct?
MR. SLATER: Objection.
You can answer.
INTERPRETER SHAO: The interpreter is asked to repeat the rendition.
THE WITNESS: I don't quite understand this question. Are you referring to the investigation on Impurity K?
BY MR. BERNARDO:
Q. No. Thank you for asking me to clarify if you don't understand, Ms. Ge.
I just want to understand what you personally did to try and get an understanding of what the memo was

Page 248

communicating.
A. After I read this -- oh, by the way, I now understand your question.
After I read this e-mail, I got very confused because this e-mail was written in such a lousy way.
In order to correctly understand what this e-mail was talking about, I did a lot of work, including reading the whole entirety of this e-mail as well as the attached patent.
I also approached relative people, including Jinsheng Lin and Peng Dong, for communication.
Afterwards, I read the entirety of the e-mail again. Then finally I got what it was communicating about. After all, this e-mail was written in such a poor way.
Q. And after you took the steps you just described, Ms. Ge, tell the jury what your understanding of what was being communicated in the memo.
A. After communication with other people, as well as my hard work, I developed

Page 249

an understanding of the communication, being this e-mail.

As seen in the title, it was about N-nitroso impurity found in the technical improvement of irbesartan, and he was trying to conduct a structural and a toxicological comparison between that impurity and the Impurity K in valsartan as well as NDMA, with NDMA being one of the naturally occurring N-nitroso compounds. That's why he included that impurity, Impurity K, and NDMA in his memo.

However, the whole e-mail was about the analysis of the impurity found in the technical improvement of irbesartan.

Q. The sentence that Mr. Slater read you -- and you can pull it up if you want to refresh your recollection -- says that what was occurring in irbesartan was similar to the NDMA that occurs in valsartan when quenched with sodium nitrite.

Do you recall that sentence?

A. As for that sentence -- hold on. Let me read it.

Page 250

I recall it. I see it now.

Q. Thank you.

Can you help the jury understand, Ms. Ge, how to reconcile that sentence with the testimony you've given today and yesterday about your understanding of the overall document?

MR. SLATER: Objection.

You can answer.

THE WITNESS: Yes, I can.

For the entirety of this e-mail, it was talking about this N-nitroso compound impurity found in the technical improvement of irbesartan.

However, this e-mail was written in such a lousy way, so in terms of the discussion on the structure, it was very confusing.

At that time he was only trying to make a comparison in structure; therefore, he was trying to find something, and he came across this patent which talked about Impurity K

Page 251

when it was generated by quenching with sodium nitrite of valsartan. And the patent did not mention NDMA at all.

When he was trying to make this structural and toxicological comparison between the impurity found in irbesartan and Impurity K, he also included NDMA because all three were in the category of N-nitroso compounds.

When he was trying to make this comparison of the nitroso compounds, he actually was trying to compare with the Impurity K found in valsartan mentioned by this patent. He included NDMA in the toxicological comparison. That is because NDMA is a very common compound.

After all, none of us had the background of toxicology or pharmacology, so it's easier for us to understand why he included NDMA in the comparison. But at that time, he was

Page 252

not aware of the existence of NDMA in valsartan.

This e-mail was written in such a lousy way, so when all the paragraphs were put together, the whole e-mail was very confusing.

BY MR. BERNARDO:

Q. I want to go back to Impurity K. I think you testified that is a nitroso compound, correct?

A. That is correct.

Q. And that patent application that Mr. Lin attached to his July 27, 2017 memo claims that Impurity K forms in valsartan, right?

A. That is correct.

Q. And at the end of the memo, Mr. Lin says that the company should pay attention to that issue, Impurity K forming in valsartan, correct?

MR. SLATER: Objection.

You can answer.

THE WITNESS: That is correct.

///

Page 253

BY MR. BERNARDO:
Q. And do you, Ms. Ge, have an understanding of whether the company, in fact, paid attention to that issue?
MR. SLATER: Objection.
You can answer.
THE WITNESS: Yes, the company did pay attention.
BY MR. BERNARDO:
Q. Explain to the jury how the company paid attention.
MR. SLATER: Objection.
You can answer.
THE WITNESS: I communicated with Dr. Lin. According to him, LC-MS was used in the analytics and the verification, and the result was that there was no Impurity K found in valsartan. This result was delivered to the technical department at Chuannan site.
BY MR. BERNARDO:
Q. I want to circle back, Ms. Ge, to the beginning of this discussion we just

Page 254

had, all the way back to plaintiffs' allegation that ZHP knew about NDMA in 2017 and hid it and didn't do anything about it.
In light of the discussion we just had the last few minutes, do those allegations even make sense to you?
MR. SLATER: Objection.
You can answer.
THE WITNESS: They make no sense to me at all. I already testified in the prior statement that before June 2018, nobody in ZHP knew about the existence of NDMA in our valsartan.
And I also told everyone that one of the most important reasons is that we were lacking a method to identify NDMA.
BY MR. BERNARDO:
Q. I want to switch gears to the FDA correspondence that Mr. Slater discussed with you.
Do you recall that correspondence? And you can pull it up, but

Page 255

I just want to talk generally about it.
A. In general, I recall the correspondence.
Q. So in that correspondence, do you recall FDA noted a number of deficiencies?
MR. SLATER: Objection.
You can answer.
THE WITNESS: In the warning letter, they noted two deficiencies.
BY MR. BERNARDO:
Q. And my question, Ms. Ge, is, are those letters that you discussed with Mr. Slater in your earlier testimony the end of the story, or did ZHP continue to work with FDA with respect to the issues discussed in the warning letter?
MR. SLATER: Objection.
You can answer.
THE WITNESS: I stated in my prior testimony, after we received this warning letter from FDA, we were very serious and careful in response. It took us several years back and

Page 256

forth with the FDA for the communication.
We also gathered a lot of manpower and relative departments for the response in order to work with FDA. We also did a lot of corrections and improvements accordingly.
Eventually FDA issued a report stating that we are -- or we were at the time of the report in compliance with cGMP.
BY MR. BERNARDO:
Q. You stole my later question, Ms. Ge. We'll get there.
Before we do, so several years you worked with the FDA. Did you provide them additional information and support of ZHP's position regarding its compliance with GMP?
MR. SLATER: Objection.
You can answer.
THE WITNESS: Yes, we did. In both the response to their warning letter and our communication with FDA,

Page 257

we had been communicating with them our position that we had always been in compliance with GMP.
BY MR. BERNARDO:
Q. And in addition to providing them communication, did you meet with FDA?
MR. SLATER: Objection.
You can answer.
THE WITNESS: To the best of my knowledge, we did.
BY MR. BERNARDO:
Q. And was there ultimately any kind of an inspection to see if the issues that they raised were addressed or if they would agree with ZHP's position?
MR. SLATER: Objection.
You can answer.
THE WITNESS: After receiving the warning letter, we responded to the warning letter. We continued to communicate with them.
So FDA arranged an on-site inspection. Afterwards they issued an EIA report stating that we were in

Page 258

compliance with GMP.
BY MR. BERNARDO:
Q. Ms. Ge, I'd like to show you what's been marked as Defense Exhibit 1A, which is the English version, and 1B which is the Chinese version.
(Whereupon, Exhibit Number Defense 1A and Defense 1B were marked for identification.)
THE WITNESS: Hold on. Let me find the Chinese version.
INTERPRETER SHAO: The interpreter could not find a link to 1A.
MR. BERNARDO: Stephanie, can you help us here?
MS. MARTIN: Yep. You probably just need to refresh. I just loaded it seconds ago.
THE WITNESS: Are you referring to 466B?
MS. MARTIN: Defense 1B.
THE WITNESS: Hold on. 1B.
MS. MARTIN: And the prefix is

Page 259

Defense, not ZHP. It's Defense 1B.
THE WITNESS: I see it. I see it.
BY MR. BERNARDO:
Q. Are you there, Ms. Ge?
A. I see it. I see it.
Q. And, Ms. Ge, what's been marked as Defense 1A and in Chinese 1B is an October 18, 2021 letter from US Food and Drug Administration.
Are you familiar with this document?
A. I've reviewed this document before.
Q. Is this document the one that you were referring to in terms of the document in which the FDA made conclusions following the several-year process we just discussed?
MR. SLATER: Objection.
You can answer.
THE WITNESS: That is correct.
The letter also says from July 19, 2021 to July 29, 2021 they

Page 260

conducted an inspection of our facility and came up with this conclusion.
BY MR. BERNARDO:
Q. I'd like to draw your attention, Ms. Ge, to the first paragraph, the middle of the first paragraph. And it says, "FDA has determined that the inspection classification of this facility is a" -- "is 'no action indicated.'" And then in parentheses it says "(NAI). Based on this inspection, this facility is considered to be in an acceptable state of compliance with regard to current good manufacturing practice." And then in parentheses it says "(CGMP)."
Do you see that?
A. Yes, I see it, indeed.
Q. And is what I just read the conclusion that FDA reached after the back-and-forth over four years that you just described in your earlier testimony with ZHP and the FDA?
MR. SLATER: Objection.

Page 261

You can answer.
THE WITNESS: That is correct. Not only based on our response to them and our communication to them, FDA also conducted an on-site inspection and verification.
Based on all the material they received, they came up with the conclusion that our facility is an NAI facility and that we are in compliance with cGMP.
BY MR. BERNARDO:
Q. And again, NAI that you just referred to means "no action indicated"?
MR. SLATER: Objection.
You can answer.
THE WITNESS: That is correct. "NAI" is one of the terms used by FDA, meaning "no action indicated."
BY MR. BERNARDO:
Q. Drawing your attention to further down on the same page, the last paragraph, it says, "FDA has concluded that this inspection is 'closed' under 21 CFR

Page 262

20.64(d)(3)."
Do you see that?
A. Yes.
Q. Do you have an understanding of what that means, Ms. Ge?
A. Not only this sentence, but also including the EIR report and the warning letter and our responses, the whole process is closed.
INTERPRETER SHAO: The interpreter would like to make a global correction if necessary, about EIR report. In the prior translation, it may be mistakenly translated as "EIA report."
A. After the inspection of facility was regarded as NAI, and they came up with the conclusion that we were in compliance with cGMP, which means that all that happened prior to that, including the warning letters, was closed. That's my understanding.
BY MR. BERNARDO:
Q. And, Ms. Ge, does this

Page 263

October 18, 2021 report go through in the following 24 pages discussions of the various deficiencies or issues that were first raised in the 2018 warning letter, to your knowledge?
MR. SLATER: Objection.
You can answer.
THE WITNESS: That is correct.
BY MR. BERNARDO:
Q. If you look way at the back of the report, Ms. Ge, on pages 22, 23, and -- I guess 22 and 23, it lists out a number of exhibits.
Do you see that?
MR. SLATER: Objection.
THE WITNESS: Yes, I see them.
MR. BERNARDO: Steph, would you bring up page 22, please?
Thank you.
BY MR. BERNARDO:
Q. And if you see in the right, Ms. Ge, it gives you page numbers, and if you add them up, there are hundreds of pages, is that fair?

Page 264

A. I believe that is the case.
Q. And do you have an understanding of what these exhibits are generally, Ms. Ge?
A. Yes, I do.
Q. And tell us what they are, please.
A. Those exhibits were the documents they reviewed and collected and brought back to FDA in their inspection in 2018. These documents are all quality documents.
Q. So these are documents that ZHP provided in support of its position during this period of back-and-forth with FDA over several years?
MR. SLATER: Objection.
THE WITNESS: That is correct. This is an incomplete list of documents we provided in the back-and-forth communication with FDA over those few years.
There are quite a few documents that were not listed here.

Page 265

BY MR. BERNARDO:
Q. Thank you, Ms. Ge.
I just want to take a minute to go through one example of an issue they discuss.
And if you could turn to page 9 of Exhibit 1A and 1B. So if you look at page -- I'm sorry.
A. I see it.
Q. Thank you.
If you look at the section -- there's a section called Customer Complaints.
Do you see that?
Or "Customer Complaint." I'm sorry.
A. Yes, I see it.
Q. And I want you to look in the middle of that paragraph, where it says, "A total of eight technical communications were investigated as complaints for unknown peaks."
Do you see that?
A. Yes, I see it.
Q. And it continues to say, "The

Page 266

firm performed the investigation and assessed if the peaks were part of the impurity profile of the API or resulted as part of the manufacturing process. The investigation report was provided to the customers."
Do you see that?
A. I see it.
Q. And do you recall Mr. Slater raised with you the issue of unknown peaks that was raised in November of 2018 and that they hadn't been investigated?
Do you recall that?
MR. SLATER: Objection.
You can answer.
THE WITNESS: I don't quite recall.
BY MR. BERNARDO:
Q. Okay. Well, let me ask you to read on with me, where it says, "None of the technical communications reviewed were related to nitrosamine issues."
Do you see that?
MR. SLATER: Objection.
You can answer.

Page 267

THE WITNESS: I see it. That's true.
BY MR. BERNARDO:
Q. So am I understanding this correctly, that FDA looked at these unknown peaks and concluded that none of them related to nitrosamine issues, is that correct?
MR. SLATER: Objection.
You can answer.
THE WITNESS: That is correct.
BY MR. BERNARDO:
Q. And going back to what we talked about on the first page, so after this investigation, as we just went over a little while ago, FDA found that ZHP was in compliance with cGMP, is that correct?
MR. SLATER: Objection.
You can answer.
THE WITNESS: That is correct.
MR. BERNARDO: Thank you, Ms. Ge.
And subject to any questions I might follow up that Mr. Slater may ask, I have no further questions at

Page 268

this point, but I do want to thank you for your time and your travel to live testimony here.
THE WITNESS: I would like also to thank you and your colleagues for your help in preparation of the three topics, because I really got a lot of help from you. Thank you.
MR. SLATER: Chris, let's put up the patent in Mandarin, ZHP01812101, please. Perfect.
(Whereupon, Exhibit Numbers were ZHP-469A and ZHP-469B were marked for identification.)
FURTHER EXAMINATION
BY MR. SLATER:
Q. Do you see on the screen is the patent we've been talking about that was referenced in Jinsheng Lin's e-mail? Do you see that on the screen?
A. Yes.
Q. And you see in the top right there's a number for the patent, 103613558.
Do you see that?

Page 269

A. Hold up. Let me find it. Are you --
Q. Top right corner.
A. -- referring to the application announcement number?
Q. Yes.
A. I see it.
Q. Great. Let's put that aside for a second and let's go to the valsartan patent investigation report now.
Have you ever seen this document?
(Whereupon, Exhibit Number ZHP-170 was marked for identification.)
A. I saw the patent application document, which was listed as one of the exhibits on the list that was shown to me previously.
BY MR SLATER:
Q. Do you see the document on the screen?
A. I see the document on the screen.

Page 270

Q. What is the title of the document?
A. It says here, "Valsartan Patent Investigation Report?
MR. SLATER: And let's go now -- let's go now to the page which is ZHP02336682.
Perfect.
Q. Do you see right there in the middle of the page the number for the patent that we've been talking about that was referenced in the Jinsheng Lin e-mail? Do you see the number right there?
A. Yes, I see it.
Q. And this document, it's my understanding from the metadata, was last modified -- well, let me actually ask it differently.
It's my understanding that this is the 2015 fourth quarter update of the valsartan patent investigation report.
Do you have any reason to doubt that?
A. Well, I don't know where you

Page 271

came up with this time point like first quarter of 2015. I've never read this document before, so I don't even know how you could come up with that number.
Q. I'm going to tell you in one second.
Wait a second. Hang on. You'll have to just bear with me for one second.
I got it. The electronic file name of the document, I'm advised, is that is the 2015 Q4 update.
So my question is this. Assuming that to be correct, ZHP actually had reviewed this patent several years before Jinsheng Lin saw it, because it would be back in, at least at the latest, 2015, a couple years earlier than his e-mail, and that would undercut everything he told you, wouldn't it?
You can answer that question.
MR. BERNARDO: Object to the form of the question.
THE WITNESS: That's not correct.

Page 272

BY MR. SLATER:
Q. If this is -- rephrase.
If I am correct that this valsartan patent investigation report that you're looking at was updated at the latest 2015 fourth quarter, that would mean that ZHP had it in its possession and had reviewed the patent no later than 2015, correct?
MR. BERNARDO: Object to the form of the question.
THE WITNESS: That's not correct. I don't know how you came up with the idea that this patent was reviewed in the fourth quarter of 2015. The document itself didn't say so.
BY MR. SLATER:
Q. Wait one second.
All right. We're putting a document up. Just so you know, we're pulling up the documentation that I believe will show the date.
Let me ask you this question. If, in fact, this patent was reviewed in 2014

Page 273

or 2015, you would agree that ZHP should have taken action in response to what it learned from the patent at that time, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: Your hypothesis is not legitimate.

Based on my communication with Jinsheng Lin and Peng Dong, it's true that they were not aware of this until 2017 after a search was conducted. Prior to that, they were not aware of this.

BY MR. SLATER:

Q. I'm going to advise you that the metadata for this document indicates that it was last modified November 4, 2014.

So based on that, your company actually did have access to this patent, and in fact, part of what your company routinely does is patent infringement analysis to make sure you're not infringing other patents, correct?

MR. BERNARDO: Object to the

Page 274

form of the question.

THE WITNESS: I don't know the patent analysis that you just mentioned. After all, I work in the quality assurance department.

Also, I was not told to be prepared for the topic of patent for this deposition.

BY MR. SLATER:

Q. You walked into this deposition with a binder containing a patent and used that as the justification for your explanation for the Jinsheng Lin e-mail, and you're saying you came here not ready to talk about a patent?

MR. BERNARDO: Object to the form of the question.

BY MR. SLATER:

Q. Specifically, the patent that you walked into this deposition expecting to talk about?

Let me rephrase it. I'm going to withdraw it and start again.

You're saying you were not

Page 275

expecting to talk about the patent that you actually have in your binder and that you prepared to talk about as part of your explanation for the Jinsheng Lin e-mail?

Is that your testimony under oath?

MR. BERNARDO: Object to the form of the question and the characterization of her testimony.

THE WITNESS: You must have misunderstood my prior testimony, because my prior testimony didn't say so.

Talking about this patent, I was told that basically I need to talk about the topic of ZHP's knowledge of NDMA. With that, this e-mail with the attached patent would be in the scope. So I prepared for that patent.

I was not prepared in general for the topic of patents.

MR. SLATER: Let's take that down.

///

Page 276

BY MR. SLATER:

Q. You went through some correspondence between ZHP and the FDA years after the FDA warning letter was sent.

Remember you just talked about that with your counsel?

A. I went through the related response, yes.

Q. None of that later correspondence indicated that ZHP didn't violate -- let me start over.

None of the -- rephrase.

None of that correspondence indicated that ZHP did not deviate from cGMP, meaning -- I've got to -- sorry, I'm tired. I'm going to start over.

MR. BERNARDO: Take three.

MR. SLATER: I'm almost done, so let's see if I can just muster enough energy to get one coherent sentence out.

BY MR. SLATER:

Q. None of that -- rephrase.

None of those communications

Page 277

from the FDA stated that ZHP was in compliance with cGMP when it was manufacturing and selling the valsartan that was contaminated with NDMA, correct?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: Your question sounds very strange to me. That is because in our response to FDA's letter, we already stated our company's position that we have been in compliance with cGMP in response to FDA's findings.

While we were working with them, we always insisted that we have been in high-quality -- high-quality compliance with GMP during all the responses to FDA.

BY MR. SLATER:

Q. The FDA obviously disagreed and felt that when you manufactured the valsartan and the manufacturing process was creating NDMA that was contaminating the pills for years, that despite ZHP thinking they were

Page 278

doing everything right, the FDA just disagreed, right?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: As in the later correspondence with the FDA, as well as the report presented by Rich just now, FDA asked us to keep providing exhibits and evidence, which we did.

After receiving and reviewing those exhibits, they also conducted an online inspection.

Finally they came to the conclusion that our facility is in the status of NAI, and in their report they also acknowledged that we were in compliance with cGMP.

BY MR. SLATER:

Q. Right.

After three years of fixing the problems, changing your manufacturing process, and taking steps to try to correct the deviations the FDA had found, after those three years or so, then they released the

Page 279

import ban and said that you were in compliance. That's what happened?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: That is incorrect. As in my prior statement, right after receiving the warning letter from FDA, we responded to FDA our position is that we were always in compliance with cGMP.

FDA did not disagree with that. Instead, they just asked us to submit more exhibits, more documents, and then they reviewed all those documents, and that's about it. So that is my first point.

Second point is that, indeed, in order to work with the FDA, we made some corrections and improvements. But that didn't mean that we were not in compliance with GMP.

BY MR. SLATER:

Q. So when the FDA said in the warning letter of November 29, 2018 that your

Page 280

methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to cGMP and your API were adulterated, the FDA was telling you they thought you were doing a good job and there were no problems?

Is that your understanding?

MR. BERNARDO: Object to the form of the question.

INTERPRETER SHAO: Sorry, the interpreter is asked for a repeat of the rendition, simply because the witness was distracted with a phone call from the front desk.

THE WITNESS: That is incorrect. Your interpretation is incorrect. That is incorrect. Your understanding is incorrect.

Actually, it is within the scope of FDA's authority to issue a warning letter to us, which they did in 2018. They also gave us the right to come up with a response.

In that response, we already

made our position very clear that we were in compliance with cGMP, but we still communicated with them.

FDA never disagreed with us. They only asked us to provide additional documents and evidence and asked us to do this, then do that, but they never disagreed with us that we were in compliance with CGMP.

After working with the FDA and submitting all the documents, eventually FDA issued this EIR report, which was shown in the approval letter.

BY MR. SLATER:

Q. You also had to change your manufacturing process so that you would not create NDMA and contaminate your valsartan with it any longer.

That's a true statement? Please say yes or no.

MR. BERNARDO: Object to the form of the question.

THE WITNESS: It is not a true

statement.

BY MR. SLATER:

Q. So ZHP continued to manufacture valsartan with the zinc chloride sodium nitrite quenching process creating NDMA, and you were allowed to keep selling valsartan with NDMA?

Is that your testimony to this jury?

MR. BERNARDO: Object to the form of the question.

THE WITNESS: This is totally incorrect.

MR. SLATER: I'm done.

MR. BERNARDO: Okay. And at the risk of being shot, I just have a few very quick questions.

MR. SLATER: Then I'm going to have more follow-up, I'm telling you right now. I'm trying to -- and this -- I can't get -- let me tell you where I'm coming from on this.

I can't get a straight answer to simple questions. Simple things

are all denied.

I was going to end the deposition just to mercifully put us out of our misery, but I will tell you right now if you ask more questions, I'm going to follow up, and I'm going to go until she finally admits basic facts.

You can do whatever you want. But I have a lot more that I would do normally, but I'm just willing to stop. But if you're going to continue, then I'm going to continue, and that's what we're going to do.

Because if I can't get a straight answer to a question -- I just spent 20 minutes trying to get her to admit such basic things; she doesn't want to do it.

You do whatever you want, but I'm coming back after you're done and I'm following up again.

MR. BERNARDO: I'm not going to go back and forth with you, Adam,

other than to say I disagree with you.

If you want to follow up the questions I have with respect to the topic and the specific questions I am asking her, you may. You may not go and reopen the deposition on other questions.

MR. SLATER: Oh, really? You mean like when you just went into documents I hadn't even asked any questions about on your questioning?

You can continue. Go ahead.

FURTHER EXAMINATION

BY MR. BERNARDO:

Q. Ms. Ge, do you have responsibility for evaluating patents for infringement?

A. No. As I stated earlier, I was not responsible for patents. I worked in the QA.

Q. Do you know what the process is for evaluating patents for patent infringement?

A. I'm not familiar with this

process at all. My scope is GMP, which has nothing to do with it.

Q. Do you have an understanding of how reports like the one that Mr. Slater showed you a few minutes ago are prepared?

A. I already stated just now, I have no idea at all.

Q. Do you know if they're even reviewed?

A. I don't know. I've never seen this document before.

MR. BERNARDO: That's all I have.

MR. SLATER: No further questions.

MR. BERNARDO: Thank you very much, Ms. Ge. I hope you have safe travels back to your home.

MR. SLATER: Very nice to see you. We'll see you in New Jersey probably at some point soon.

THE VIDEOGRAPHER: The time right now is 1:17 p.m. We're off the record.

(Whereupon, the deposition was concluded.)

CERTIFICATE

I, MAUREEN O'CONNOR POLLARD, Registered Diplomate Reporter, Realtime Systems Administrator, and Certified Shorthand Reporter, do hereby certify that prior to the commencement of the examination, JUCAI GE, was remotely duly identified and sworn by me to testify to the truth, the whole truth, and nothing but the truth.

I DO FURTHER CERTIFY that the foregoing is a verbatim transcript of the testimony as taken stenographically by and before me at the time, place, and on the date hereinbefore set forth, to the best of my ability.

I DO FURTHER CERTIFY that I am neither a relative nor employee nor attorney nor counsel of any of the parties to this action, and that I am neither a relative nor employee of such attorney or counsel, and that I am not financially interested in the action.

_____

MAUREEN O'CONNOR POLLARD
NCRA Registered Diplomate Reporter
Realtime Systems Administrator
Certified Shorthand Reporter
Notary Public

Dated: June 2, 2022

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

ERRATA

PAGE LINE CHANGE

____ ____ _____

REASON: _____

___ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

ACKNOWLEDGMENT OF DEPONENT

I, _____, do Hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

WITNESS NAME DATE

Subscribed and sworn
To before me this
_____ day of _____, 20____.

My commission expires: _____

_____

Notary Public

LAWYER'S NOTES

PAGE LINE

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____

____ ____ _____